K083618

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter Information:
PACSGEAR, Inc.
7020 Koll Center Pkwy.
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Pleasanton, CA 94566

JAN 2 8 2009

Date Summary Prepared:
July 2, 2008

Contact Person:
Ian P. Gordon
Emergo Group, Inc.
Telephone: 512-327-9997
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Device Name:
Trade Name(s): PacsSCAN Medical Imaging Software with QC Module
Classification Name: Image Processing System
Classification Regulation: 892.2050
Panel: Radiology
Product Code: LLZ

Predicate Device Information:
Device Name: RadWorks Medical Imaging Software with Quality Control Module
Manufacturer: Applicare Medical Imaging, B.V.
Reference: K982862

Device Description:
The PacsSCAN Medical Imaging Software with QC Module is intended to be used by authorized staff to perform various quality control operations on PacsSCAN imaging studies before they are made available to other locations in the network. These operations include digitizing film images, capturing video images, confirming or editing patient demographics, reviewing the history of the study, adding or removing images, combining with another study, renumbering images, editing patient orientation information, and setting or editing routing information.

Intended Use:
The PacsSCAN Medical Imaging Software with QC Module is intended to be used by authorized staff to perform various quality control operations on PACSGEAR imaging studies before they are made available to other locations in the network. These operations include scanning film images, capturing video images, confirming or editing patient demographics, reviewing the history of the study, adding or removing images, combining with another study, renumbering images, editing patient orientation information, and setting or editing routing information.

Comparison to Predicate Device:

Specification	PACSGEAR Medical Imaging Software	RadWorks Medical Imaging Software
Digitize film	Yes	Yes
Capture video	Yes	Yes
Edit patient demographics	Yes	Yes
Review reports/study history	Yes	Yes
Add/remove images	Yes	Yes
Combine studies	Yes	Yes
Renumber Images	Yes	Yes
Edit patient orientation information	Yes	Yes
Set/edit routing information	Yes	Yes
Image review	Flip/Rotate/Pan/Zoom	Flip/Rotate/Pan/Zoom
JPEG lossy/lossless compression	Yes and JPEG2000 lossy/lossless compression	Yes
LUT compensation	Yes (automatic)	Yes (manual)
Image processing (image segmentation, image smoothing)	Yes	Yes
DICOM Print	Yes	Yes

Testing and Conclusions:
Software validation has established the device's ability to meet its intended use and established specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

PACSGEAR, Inc.
c/o Mr. Ian Gordon
Senior Vice President
Emergo Group, Inc.
1705 S. Capitol of Texas Highway, Suite 500
AUSTIN TX 78746

JAN 2 8 2009

Re: K083618
Trade/Device Name: PacsSCAN
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 20, 2008
Received: December 9, 2008

Dear Mr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083618

Device Name: PacsSCAN Medical Imaging Software with QC Module

Indications for Use: The PacsSCAN Medical Imaging Software with QC Module is intended to be used by authorized staff to perform various quality control operations on PACSGEAR imaging studies before they are made available to other locations in the network. These operations include scanning film images, capturing video images, confirming or editing patient demographics, reviewing the history of the study, adding or removing images, combining with another study, renumbering images, editing patient orientation information, and setting or editing routing information.

Prescription Use ___XX___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K083618